

## AMENDMENTS

### In the Claims:

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Currently Amended) A system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest, comprising:

- a selector for identifying at least one substance of interest;
- a profiler for selecting from multiple profiles related to safety of the at least one substance of interest, using at least one filter to determine at least one set of cases;
- at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter; and
- an output device for displaying analytic results from the data mining engine,

wherein the substance of interest is assessed in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements.

2. (Previously Presented) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 1, wherein the at least one data mining engine is a proportional analysis engine to assess deviations in a set of reactions to the at least one substance of interest.

3. (Previously Presented) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 1, wherein the data mining engine is a comparator to measure reactions to the at least one substance of interest against a user-defined backdrop.

4. (Currently Amended) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 1, wherein the data mining engine is a correlator to look for correlated signal characteristics in drug/reaction/demographic information at least one of drug information, reaction information and demographic information.

5. (Previously Presented) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 1, wherein the data mining engine is at least two members of the group consisting of a proportional analysis engine, a comparator, and a correlator.

6. (Canceled).

7. (Previously Presented) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 1, wherein the system permits assessment and analysis of risks of adverse effects resulting from use of at least one substance of interest in any of multiple dimensions of risk assessment and analysis.

8. (Currently Amended) A system for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest, comprising:

a selector for identifying at least one drug of interest;

a profiler for selecting from multiple profiles related to safety of the at least one drug of interest, using at least one filter to determine at least one set of cases;

at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter; and

an output device for displaying analytic results from the data mining engine,

wherein the drug of interest is assessed in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements.

9. (Previously Presented) The system for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 8, wherein the at least one data mining engine is a proportional analysis engine to assess deviations in a set of the reactions to the drug of interest.

10. (Previously Presented) The system for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 8, wherein the

data mining engine is a comparator to measure reactions to the drug of interest against a user-defined backdrop.

11. (Currently Amended) The system for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 8, wherein the data mining engine is a correlator to look for correlated signal characteristics in at least one of drug information, reaction information and demographic information.

12. (Previously Presented) The system for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 8, wherein the data mining engine is at least two members of the group consisting of a proportional analysis engine, a comparator, and a correlator.

13. (Canceled).

14. (Previously Presented) The system for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 8, wherein the system permits assessment and analysis of risks of adverse effects resulting from use of at least one drug of interest in any of multiple dimensions of risk assessment and analysis.

15. (Previously Presented) A method for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest, comprising:

identifying the at least one substance of interest;

selecting a profile of the at least one substance of interest related to safety of the at least one substance of interest, using at least one filter to determine at least one set of cases;

analyzing risks of adverse effects resulting from use of the at least one substance of interest using at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter; and

displaying results from analyzing risks of adverse effects resulting from the use of the at least one substance of interest.

16. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 15, wherein the at least one data mining engine is a proportional analysis engine to assess deviations in a set of the reactions to the at least one substance of interest.

17. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 15, wherein the at least one data mining engine is a comparator to measure reactions to the at least one substance of interest against a user-defined backdrop.

18. (Currently Amended) The method for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 15, wherein the at least one data mining engine is a correlator to look for correlated signal characteristics in at least one of drug information, reaction information and demographic information.

19. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 15, wherein the data mining engine is at least two members of the group consisting of a proportional analysis engine, a comparator, and a correlator.

20. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 18, wherein the at least one substance of interest is assessed in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements.

21. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 18, wherein the method permits assessment and analysis of risks of adverse effects resulting from use of at least one substance of interest in any of multiple dimensions of risk assessment and analysis.

22. (Currently Amended) A method for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest, comprising:

identifying the at least one drug of interest, as well any other drugs, nutrients, supplements, and other substances;

selecting a profile of the at least one drug of interest related to safety of the at least one drug of interest, using at least one filter to determine at least one set of cases;

analyzing risks of adverse effects resulting from use of the at least one drug of interest using at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter; and

displaying results from analyzing risks of adverse effects resulting from the use of the at least one drug of interest,

wherein the at least one drug of interest is assessed in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements.

23. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 22, wherein the at least one data mining engine is a proportional analysis engine to assess deviations in a set of the reactions to the at least one drug of interest.

24. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 22, wherein the at least one data mining engine is a comparator to measure reactions to the at least one drug of interest against a user-defined backdrop.

25. (Currently Amended) The method for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 22, wherein the at least one data mining engine is a correlator to look for correlated signal characteristics in at least one of drug information, reaction information and demographic information.

26. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 22, wherein the

data mining engine is at least two members of the group consisting of a proportional analysis engine, a comparator, and a correlator.

27. (Canceled).

28. (Previously Presented) The method for assessing and analyzing risks of adverse effects resulting from use of at least one drug of interest according to Claim 22, wherein the method permits assessment and analysis of risks of adverse effects resulting from use of at least one drug of interest in any of multiple dimensions of risk assessment and analysis.

29. (New) The method of Claim 8, wherein the proportional analysis further comprises comparing the drug of interest to a second drug of interest in a same therapeutic category for the drug of interest selected.

30. (New) The method of Claim 8, wherein the proportional analysis further comprises comparing the drug of interest to a second drug of interest in a second therapeutic category.

31. (New) The method of Claim 8, further comprising:  
a Bayesian filtering, wherein the Bayesian filtering includes providing a statistical cut-off threshold to reduce the effect of drugs or reactions accounting for less than a certain percentage of cases of adverse drug events.

32. (New) The method of Claim 8, further comprising:  
comparing clinical trial data, wherein the comparison includes comparing the potential and actual adverse effects of the drug of interest in a pre-market environment to that of the potential and actual adverse effects of the drug of interest in a post-market environment.

33. (New) A system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest, comprising:  
a selector for identifying at least one substance of interest;

a profiler for selecting from multiple profiles related to safety of the at least one substance of interest, using at least one filter to determine at least one set of cases;

at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter; and

an output device for displaying analytic results from the data mining engine,  
wherein the substance of interest is assessed in combination with other drugs,  
foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements and  
wherein the assessment of the substance of interest includes comparing the potential and actual adverse effects of a substance of interest in a pre-market environment to that of the potential and actual adverse effects of a substance of interest in a post-market environment.

34. (New) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 33,

wherein the drug of interest identified by the selector is a target drug;  
wherein the target drug is profiled in relation to a one or more concomitant drugs;  
wherein the profiler identifies a one or more concomitant drug dimensions;  
wherein the one or more concomitant drugs were prescribed in one or more cases where the target drug was also prescribed;

wherein the one or more prescriptions are configured to result in an adverse drug reaction report; and

wherein the adverse drug reaction is configured so as to be reported in an adverse effects reporting database.

35. (New) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 34,

wherein the profiler is configured to label the one or more drugs are labeled as a suspect drug or a non-suspect drug;

wherein the profiler is configured to analyze a patient information, the patient information further comprising a plurality of categories for patients whose information is reported in an adverse drug effects reporting database;

wherein the plurality of categories analyzed includes a plurality of age groups, a male gender, a female gender, and a plurality of ages between 16 years old and 75 years old.

36. (New) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 35,

wherein the display is configured to show the one or more drugs are labeled as a suspect drug or a non-suspect drug;

wherein the display is configured to present a report showing the number of adverse drug effect event reports in each year during a decade;

wherein a drug detail section of the report involves paging and sorting;

wherein the report is configured to be broken down into individual years of birth of a patient who experienced an adverse drug effect reported in an adverse drug effects reporting database;

wherein the report is configured to show a plurality of serious outcomes;

wherein the report is configured to show serious outcomes in the report in a plurality of colors;

wherein the report is configured to provide a table of outcomes, a count, and percentages of the outcomes in each category;

wherein the report is configured to present a total number of serious outcomes and a total number of non-serious outcomes.

37. (New) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 33,

wherein the filtering is configured to be applied individually, as a group, and globally;

wherein the filtering is configured to be retained for later use;



wherein the filtering is configured to be applied repeatedly;  
wherein two or more filters are configured to be merged;  
wherein the filter is configured to be overwritten; and  
wherein the filter is configured to be saved as an incremental filter.

38. (New) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 33, further comprising:

a pre-filter, wherein the pre-filter is configured in a first state to switch on an indication-related adverse drug reaction and  
wherein the pre-filter is configured in a second state to switch off an indication-related adverse drug reaction.

39. (New) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 33,

wherein the analysis is configured to search for a signal;  
wherein the signal is selected from among the group consisting of an anomaly in a random population reported in an adverse effects reporting database, a change against a known background, or a coherent target in a noise background; and  
wherein the signal is detected by a proportional analysis engine, a differencing engine, and the correlator.

40. (New) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 39,

wherein the correlator is configured to measure a degree of an association according to a correlation algorithm;

wherein the correlator is configured to rank a first pair of terms relative to a second pair of terms; and

wherein the correlator is configured to calculate a strength of the association for a known factor and for a rare adverse drug effect.

wherein the display presents the results of a correlated search.

41. (New) The system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest according to Claim 40, wherein the association is a drug and a reaction or a patient age and an outcome.